THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

LISSA M. ROHLIK, Plaintiff, v. I-FLOW CORPORATION, Defendant.	Case No. **7**:10-CV-00173-F

I-FLOW CORPORATION'S REPLY BRIEF IN SUPPORT OF ITS RULES 12(b)(6) AND 9(b) MOTION TO DISMISS AND RULE 12(f) MOTION TO STRIKE

Defendant, I-Flow Corporation ("I-Flow"), replies as follows in support of its Motion to Dismiss and to Strike Plaintiff's Complaint:

I. INTRODUCTION

Rule 9(b) of the Federal Rules of Civil Procedure creates a heightened pleading standard in cases alleging fraud or mistake, requiring that "the circumstances constituting fraud or mistake shall be stated with particularity." FED. R. CIV. P. 9(b). Plaintiff's complaint fails to satisfy this pleading standard. Further, Plaintiff fails to dispute the pleading standard required for her common law fraud and UDTPA claims. Instead, she relies upon a court order entered in the District Court of Arizona, based on Arizona law, which is inapposite to this case. Furthermore, Plaintiff attempts to turn the doctrine of federal preemption on its head in what amounts to a vain effort to establish that *Buckman* is not applicable here. For the reasons set forth here and in its initial Motion, I-Flow's Motion to Dismiss and Motion to Strike Plaintiff's Complaint should be granted, with prejudice.

II. ARGUMENT

A. PLAINTIFF'S FRAUD CLAIMS ARE NOT PLED WITH THE REQUISITE PARTICULARITY TO SUSTAIN A MOTION TO DISMISS.

1. Common Law Fraud

In support of her claims under common law fraud, Plaintiff attempts to rely on an unpublished court order from the District Court of Arizona in a case against I-Flow. Interestingly, Plaintiff would like the Court to rely on this court order but then asks it to ignore persuasive authority cited by I-Flow where the federal pleadings standards for fraud are applied to medical device cases just like this one. Plaintiff makes certain to argue that a court is to look to its own state law to determine the circumstances required of a complaint to satisfy the Rule 9(b) pleading standard but then, in the next breath, asks this Court to blindly accept the unpublished ruling of a federal court in Arizona without providing the factual allegations in that particular case. (Dkt. #15, at 6, fn 2).

Specifically, Plaintiff asks this Court to rely on Honorable Susan R. Bolton's ruling in *Patton v. I-Flow Corp.* that the plaintiff in that case alleged fraud with the requisite particularity under Arizona law. (Pl. Resp. Br., Ex. A). In so ruling, Judge Bolton relied on plaintiff's allegation that "I-Flow issued a press release in 1998 stating that the FDA approved the PainBuster pain pump for orthopedic uses-as opposed to simply soft tissue and body cavity uses-when the FDA had issued no such approval." (Pl. Resp. Br., Ex. A, at 7). In fact, Judge Bolton held that "[t]his allegation of a material false statement standing alone meets the particularity requirements of Rule 9(b)." (Pl. Resp. Br., Ex. A, at 7). However, under North Carolina law, this single allegation is insufficient to sustain a claim for common law fraud because it fails to allege with particularity detrimental reliance and damages proximately flowing from that

reliance. *Frank M. McDermott, Ltd. v. Moretz*, 898 F.2d 418, 421 (4th Cir.1990). The unpublished decision in *Patton*, therefore is not controlling or persuasive here.

Other than insufficient, generic allegations of reliance, Plaintiff fails to specifically reference any misrepresentations upon which Plaintiff or her physician relied and which led to her alleged injury. Plaintiff even points this Court to the I-Flow sales representative who allegedly dealt directly with Plaintiff's physician but fails to identify any material misrepresentation by the sales representative. (Dkt. 15, at 7). Plaintiff's fraud claim fails under North Carolina law because she fails to state any allegations regarding the purported reliance by Plaintiff or her physicians.

2. UDTPA claim

Plaintiff's UDTPA claim is nothing more than a claim based on breach of warranty. Plaintiff attempts to distinguish the case at hand from the facts of *Kelly v. Georgia-Pacific LLC*, where she alleges that "…I-Flow's misconduct was so egregious that it warrants an award of punitive damages." (Dkt. #15, at 10). Plaintiff argues that this allegation, along with her allegations that I-Flow misrepresented that its pain pumps contained a superior design, rises to the level of egregious and aggravating conduct. However, it is clearly established under North Carolina law that even an intentional breach of contract does not rise to an unfair or deceptive trade practice. *Kelly v. Georgia-Pacific LLC*, 671 F.Supp.2d 785, 799 (E.D.N.C. 2009). Plaintiff's allegations suffer from the same deficiencies that were seen in *Kelly* because she alleges nothing more than a breach of contract. This is insufficient under North Carolina law and therefore, her UDTPA claims must be dismissed.

B. PLAINTIFF'S FRAUD AND NEGLIGENT MISREPRESENTATION CLAIMS ARE PREEMPTED BY FEDERAL LAW.

Plaintiff's fraud and negligent misrepresentation claims are grounded in alleged violations of FDA regulations and therefore, are preempted by federal law. Plaintiff erroneously contends that federal preemption only applies to Class III medical devices and not the Class II medical device at issue in this case. Plaintiff provides no legal authority to support this contention. Further, Plaintiff's attempt to apply inapposite case law here evidences the weaknesses of her argument.

First, Plaintiff argues that *Buckman Co. v. Plaintiffs' Legal Comm.* is distinguishable because it dealt with representations made by the manufacturer to the FDA, while the allegations in this case are predicated on purported representations made to the Plaintiff, Plaintiff's physicians and the general public. 531 U.S. 341, 121 S.Ct. 1012 (2001). Plaintiff goes so far as to say that because she does not call into question alleged misrepresentations made to the FDA, that there is no way it can be "fraud-on-the-FDA." However, the same argument was made and rejected by the U.S. Supreme Court in *Buckman*. *Id.* As I-Flow argued in its initial brief, and Plaintiff has failed to contradict, Plaintiff's claims all boils down to events that supposedly occurred between I-Flow and the FDA. That is just a fraud-on-the-FDA claim in different clothing, which is clearly barred by *Buckman*.

In *Buckman*, the defendant-manufacturer included fraudulent misrepresentations in its 510(k) submission to the FDA, and the FDA cleared the defendant's medical device based on that fraudulent submission. *Id.* Here, Plaintiff contends that I-Flow promoted its device for an off label use not cleared by the FDA. Plaintiff's fraud based claims, however, are based on the notion that I-Flow fraudulently withheld information from the FDA in order to secure clearance for its device, and then sold the device for use in a manner inconsistent with that clearance.

These purported "fraud by omission" allegations lie at the heart of Plaintiff's fraud based claims. Therefore, those claims are federally preempted as discussed in *Buckman.*

Second, Plaintiff's reliance on *Medtronic* is misplaced, just as it was misplaced by the plaintiff-petitioner in *Buckman*. It is irrelevant that Plaintiff continues to allege that misrepresentations were made to the Plaintiff, her physician and the general public and not directly to the FDA. Her allegations are still based on I-Flow's intended use of the device, the essential link that but-for the manufacturer's alleged fraud, the allegedly defective device would not have reached the market. *See Buckman, supra*.

The Court in *Buckman* distinguished the facts of *Medtronic* and that distinction applies to the case at hand. In *Medtronic*, the claims arose from the manufacturer's alleged failure to use reasonable care in the *production* of the product, not solely from the violation of FDCA regulations. *Buckman*, 531 U.S. at 353, 121 S. Ct. at 1020. In the case at hand, as was the case in *Buckman*, "the fraud claims exist solely by virtue of the FDCA disclosure requirements." *Id*.

Third, Plaintiff's reliance on *Courick v. Wyeth, Inc.*, is also misplaced. The Court in *Couick* addressed the fact that the manufacturer concealed, from physicians, serious side effects caused by prolonged use of metoclopramide, a claim which would exist based on traditional state tort law principles regardless of whether or not there existed a violation of the FDCA. 2009 WL 4644394, (W.D.N.C.). In other words, the fraudulent concealment of known side-effects had nothing to do with misrepresentation to the FDA regarding clearance of the device. Plaintiff incorrectly summarizes the holding in *Couick* by stating that the Court distinguished it from the *Buckman* plaintiffs' fraud claims that were based on misrepresentations made by a manufacturer to the FDA versus misrepresentations made to patients and doctors. (Dkt. #15, at 13). This, however, was not the holding in *Couick.* In fact, that court did not simply distinguish *to whom*

the representations were made, but instead focused on *what* the actual alleged misrepresentations were. *Courick v. Wyeth, Inc.*, 2009 WL 4644394, (W.D.N.C.) (the focus is on the fraud that is allegedly perpetrated against the patients and doctors rather than the FDA).

Accordingly, because Plaintiff's fraud and negligent misrepresentation claims are grounded in federal law and based upon alleged violations of FDA regulations, the claims are clearly preempted by federal law and must be dismissed.

III. CONCLUSION

For the reasons set forth herein, as well as in its initial Motion to Dismiss and to Strike, I-Flow requests that this Court enter an order dismissing, with prejudice, Counts II, III, VI and VII of Plaintiff's Complaint.

Dated: December 21, 2010

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CERTIFICATE OF SERVICE

I hereby certify that on December 21, 2010, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following parties:

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This the 21st day of December, 2010.

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